



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,951	11/27/2000	Charles E. Weeks	HOLISED.033A	6317

26551 7590 01/29/2003

HOLLIS-EDEN PHARMACEUTICALS, INC.  
4435 EASTGATE MALL  
SUITE 400  
SAN DIEGO, CA 92121

EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/554,951

Applicant(s)

WEEKS, CHARLES E.

Examiner

San-ming Hui

Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 December 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1-11 and 22-38.

Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200

### **ADVISORY ACTION**

Continuation of 2):

The proposed amendments filed December 18, 2002 raised new issue that requires new search and consideration for the examiner. For example, the limitation "arthritis-related tissue inflammation" recited in claim 22 on page 1 of the amendment received December 18, 2002 raises a new issue for consideration and search for the examiner. The proposed amendments filed December 18, 2002 also include new matter in claim 26. The limitation "connective tissue inflammation" has not disclosed in the originally filed specification or claims. Moreover, the expression "arthritis-related tissue inflammation" is still not clear as to what inflammation(s) is(are) encompassed by the claims. It is not clear what term "arthritis-related" refers to. What exactly the relationship between arthritis and the inflammation? Can they be indirectly related? For example, if a patient suffered from arthritis fell down because of stiffness he experiences, and fell down, and got injured such as broken ribs. The broken ribs may cause tissue inflammation, such as swelling and pain. Then the question is: is this tissue inflammation related to the arthritis or not? Since the instant specification has not clearly define what the metes and bounds of the term "arthritis-related tissue inflammation", the claims are still properly rejected under 35 USC 112, second paragraph. In view of the above reasons and the prosecution on merits is closed for the instant case, such amendments would raised new issues that requires new search and consideration for the examiner.

Art Unit: 1617

Continuation of 5):


Applicant's arguments filed December 18, 2002 regarding the pharmacological differences between instant compound and DHEA have been considered, but are not found persuasive. Applicant's arguments are not supported by evidences. Without showing any evidence to the contrary, the herein claimed claims would still be renders obvious in view of the cited prior art.

No unanswered rebuttal arguments are seen to be present. Since the proposed amendments filed December 18, 2002 will not be entered, the rejections set forth in the previous office action mailed July 16, 2002 remain.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200